FAX COVER SHEET

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FDA/Center for Devices and
Radiological Health
Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

TO: See addressee on next page
FROM: 510(k) Document Mail Center

Comments: Fax copy of the letter being mailed to you.

EXHIBIT
H

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Boston Scientific
% Ms. Michelle M. Berry
Senior, Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

JUN 17 2008

Re: K081048
Pinnacle Pelvic Floor Repair Kit II
Dated: April 11, 2008
Received: April 14, 2008

Dear Ms. Berry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require you address the following deficiencies.

1. The name of your subject device is the "Uterine Preservation" mesh. This device name implies that your device is to be used to preserve the uterus. In addition, although your proposed intended use for the subject device is for uterine prolapse repair, you have not provided any clinical data to support the safe and effective use of this mesh specifically for uterine prolapse where the uterus is not removed. Rather you are seeking substantial equivalence of the subject device to predicate devices with general intended uses for reinforcement of the pelvic floor. Therefore, please revise your device name to remove the implication that the mesh to be used for uterine preservation or uterine prolapse repair.

2. You describe two device specification changes, listed below. Please provide a complete description of how the new release criteria were determined (including any clinical or pre-clinical data) and the testing conducting to validate the safety and effectiveness of the subject device for use as intended with the new release criteria.

   - The mesh/leg tensile specification was increased from ≥2.25 lbs (reported in K071957) to ≥4 lbs. With a clinically relevant maximum sleeve removal force of 4 lbs the device requirement is that the mesh/leg integrity exceeds the force to remove the sleeve. This specification change is in agreement with the other design specification. Design verification testing met the revised acceptance criteria.

   - The sleeve removal specification was increased from ≥2.0 ± 1.5 lbs (reported in K071957) to 2.25 ± 1.75 lbs; the maximum force to remove the sleeve was increased approximately 14%. The process settings initially established for welding the mesh to

the sleeve were affected by subsequent handling during the manufacturing process resulting in product not meeting specification. The weld settings were modified to produce a stronger weld between the materials. The specification was increased to ensure weld integrity at time of use. Design verification testing was repeated and product results me the revised acceptance criteria.

3. You have provided draft labeling for your subject device. It also appears that this same draft labeling will be packaged with your predicate Pinnacle Mesh System as well as the subject device. You highlight several labeling changes you propose to reflect the inclusion of the subject device as well as other safety information for your Pinnacle mesh devices. However, deficiencies exist in your draft labeling. Some of these deficiencies pertain to labeling changes you had committed to execute, upon FDA request, for your predicate Pinnacle Mesh, K071957, which are not present in your draft labeling. Please address the following deficiencies and provide revised labeling for review.

   a. As outlined in deficiency #1, your proposed device name of "uterine preservation" is not appropriate as no clinical data has been provided to support its use during uterine preservation surgery or for uterine prolapse repair. Please remove all references to uterine preservation, use in pelvic floor repair without hysterectomy, and mesh design/configuration for performing uterine prolapse repair.

   b. Please include the following two statements immediately following the statement beginning with "Federal law restricts these devices to sale..." on the first page of your labeling. We request that these statements be included in your labeling due to the risks assessed from the analysis of FDA adverse event reports for similar types of mesh devices used in reinforcement of the pelvic floor.

      i. Training on the use of the Pinnacle Pelvic Floor Repair Kits is recommended and available. Contact your company sales representative to arrange for this training. Physicians should have experience in the management of complications resulting from procedures using surgical mesh.

      ii. The safety and effectiveness of the Pinnacle Pelvic Floor Repair Kits compared to conventional surgical repair for pelvic organ prolapse have not been demonstrated in randomized controlled clinical trials. In the United States, substantial equivalence of the Pinnacle Pelvic Floor Repair Kits to synthetic mesh has been demonstrated through benchtop testing.

   c. Please relocate your indications for use to be placed before your device description. The contraindications should also be relocated to immediately follow your indications for use.

d. On page 130 of your premarket notification, you describe that the Capio Suture Capturing device has been designed for use only during open surgical procedures. Please include in your device description and a warning that the Capio Suture Capturing device has been designed for use only during open surgical procedures.

e. In your device description, the text describes the placement of one of the mesh straps through the sacrospinous ligament. However, in other parts of the labeling the levators are referenced as an anatomical landmark. In the labeling submitted for review in predicate Pinnacle Mesh System K071957, only the levators are referenced and not the sacrospinous ligament. Please clarify and provide clinically relevant data to support the changes in anatomical location of mesh strap placement.

f. Please clarify and provide clinically relevant data to support the change in device description language from "The white dilators define the proximal end of the device and blue dilators the distal end" (present in the labeling submitted for review in predicate Pinnacle Mesh System K071957) to "The white dilators identify the leg assemblies to be placed into the arcus tendineus and blue dilators the leg assemblies to be placed into the sacrospinous ligament."

g. Please include the following warnings:

   i. A digital rectal exam should be performed to detect possible rectal perforation.

   ii. Cytoscopy is recommended to confirm bladder integrity or detect possible bladder or ureteral perforation (corresponding to this, the sponsor should remove the statement re: cytoscopy in the directions for use, p. 153).

   iii. Mild to moderate incontinence may occur due to incomplete support.

h. Please include the following precautions:

   i. As anatomy of individual patients may vary greatly, for each procedure it is important that the intended planes for device advancement and the intended place for suture placement are planned and known for each individual patient. Employment of imaging methods before and after mesh placement may aid in proper mesh placement and confirm absence of injury to non-target anatomical structures.

   ii. Do not affix mesh with any staples, clips, or clamps as mechanical damage to the mesh may occur.

i. You have suggested major changes to your adverse events listing. We do not agree with any of your changes and we do not consider any of the individual adverse events

as redundant. For example, hematoma, hemorrhage, and post-operative bleeding are not necessarily expected from a listed adverse event of bleeding. Similarly, sepsis and abscess formation should not be replaced with infection. Please refrain from making any of your suggested changes.

j. In addition to the adverse events listing present in your labeling, please include the following adverse events: vessel perforation, ureter obstruction, wound dehiscence, mesh and/or tissue contracture, edema, erythema, infection potentiation, acute or chronic inflammation, and dehiscence and/or necrosis.

k. There are a large number of adverse events reported to the FDA regarding tip breakage of the Capio Suture Capturing device. Please include instruction on how to manage such an adverse event during surgery.

l. Please include the following references along with direction for physicians to review the latest literature available on the use of synthetic mesh for reinforcement of the pelvic floor.

   i. Huebner M, Hsu Y and Fenner DE. The use of graft materials in vaginal pelvic floor surgery. International Journal of Gynecology and Obstetrics 2006; 92:279-288.

   ii. Altman D and Falconer C. Peri-operative morbidity using transvaginal mesh in pelvic organ prolapse repair. Obstetrics and Gynecology 2007; 109 (2, part I): 303-308.

4. During the review of your predicate Pinnacle Mesh System, K071957, you were requested to develop patient labeling for your device. To this request, you stated that patient labeling is available for the predicate device. Similarly, we request that patient labeling be made available for your subject device. This patient labeling should reflect all the safety and effectiveness information present in the physician labeling. Please submit patient labeling for review.

5. Your device is described as containing dyes, such as phthalocyaninato(2-) copper. However, you have not provided any statement as to whether the use of these dyes comply with FDA regulations on the use of color additives in medical devices, such as 21 CFR §74.3045. Please provide documentation that the all dyes used in your device comply with FDA regulations on the use of color additives in medical devices.

6. You state that functional testing on the proposed pinnacle kits will be completed for 1 year accelerated aging prior to launch and subsequently to launch a 3 year real time and accelerated aging will be completed. However, you have not stated the length of shelf life with which the device will be labeled. You also have not provided any data to support device

stability. Please provide the proposed shelf life for your device and stability data to support this shelf life for your device.

7. You describe that the finished device contains latex. However, no specific description is provided on which device component contains latex. Please describe which component of your finished device contains latex and include in your labeling, as appropriate, that the use of your device components containing latex are contraindicated for patients with latex sensitivity.

8. The material safety data sheet (MSDS) provided for the Marlex material states that the product use is for coatings. In this MSDS there is a medical application caution that states "do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues." Please provide a rationale why your mesh material is safe for use as a permanent implant device contrary to what is stated in the MSDS provided for the Marlex material.

9. You have provided a Truthful and Accurate Statement and 510(k) Summary as required content for a premarket notification. However, minor errors are present in these documents. Please correct these errors and provide revised a Truthful and Accurate Statement and 510(k) Summary.

    a. Your truthful and accurate statement makes reference to an incorrectly cited regulation. Please revise the regulation citation to 21 CFR §807.87(k).

    b. The Ethicon Prolift premarket notification document number should be K071512 and not K013718.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the document titled "A Suggested Approach to Resolving Least Burdensome Issues" located at http://www.fda.gov/cdrh/modact/leastburdensome.html.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do

so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at www.fda.gov/cdrh/ode/guidance/1655.html.

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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If you have any questions concerning the contents of the letter, please contact Jiyoung M. Dang, Ph.D. at (240) 176-3631. If you need information or assistance concerning the IDE

regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David Krause

David Krause, Ph.D.
Chief, Plastic and Reconstructive
Surgery Branch
Division of General, Restorative
and Neurological Devices